UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,323	07/09/2003	Laurence A. Cole	MBHB 03-411-A	1369

7590 05/30/2006

COLEMAN SUDOL SAPONE, P.C.
714 Colorado Avenue
Bridgeport, CT 06605-1601

EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,323	COLE, LAURENCE A.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *17-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Election filed 04/24/06 in response to the Office Action of 03/16/06 is acknowledged and has been entered.

Applicant's election with traverse of Group I, claims 1-16 is acknowledged. The traversal is on the ground(s) that a search and examination of all of the inventions would not impose a serious burden on the examiner. This is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions that are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in the Action mailed 03/16/06.

Although the inventions are classified similarly, the classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. For example, there are numerous methods of determining the level of ITA and its relationship to various disease states in the art. Thus, the different methods of each Group would require independent searching separate from the other Groups. For these reasons, the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-45 are pending.

Claims 17-45 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1-16 are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determining the **total** amount of hCG in claim 1, b., as taught in the specification on page 6, lines 4-7. This allows determination of the percentage of hCG that is ITA.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobata (Biochimie, 1988, 70: 1575-1585).

The claims are drawn to a method of detecting the presence or absence of invasive trophoblast cells in a biological sample wherein the biological sample is urine comprising the steps of: a. obtaining a biological sample from a patient; b. measuring an amount of hCG in the biological sample; c. measuring an amount of ITA in the biological sample; and d. determining the percentage of hCG that is ITA, wherein invasive trophoblast cells are detected if the percentage is 30% or greater.

Kobata teaches a method obtaining a biological sample wherein the biological sample is urine from a patient previously diagnosed with a trophoblastic disease (pg. 1582, right column and Figure 9). Additionally, Kobata teaches measuring total hCG and the percentage of hCG that is hyperglycosylated hCG (page 1582, right column and Figure 9), which is ITA. Finally, Kobata teaches the amount hCG that is ITA is greater than 30% in invasive mole and choriocarcinoma patients and less than 30% in the samples from hydatidiform mole patients (Figure 9).

Claims 1-5, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Cole et al. (Prenatal Diagnosis, 1999, 19: 351-359).

The claims are drawn to a method of detecting the presence or absence of invasive trophoblast cells in a biological sample wherein the biological sample is urine comprising the steps of: a. obtaining a biological sample from a patient; b. measuring an amount of hCG in the biological sample; c. measuring an amount of ITA in the biological sample; and d. determining the percentage of hCG that is ITA, wherein invasive trophoblast cells are detected if the percentage is 30% or greater.

Cole et al. teach a method obtaining a biological sample wherein the biological sample is urine from a patient (pg. 352, left column). Additionally, Cole et al. teach measuring intact and total hCG and measuring the β hCG subunit (pg. 352, right column and Table 1). Furthermore, Cole et al. teach measuring hyperglycosylated hCG (page 352, right column and Table 1). Finally, Cole et al. teach measuring the percentage of hCG that is ITA (Table 1). The specification teaches that trophoblast cells are the source of hCG (pg. 4, 3rd para.) and ITA is produced by invasive cytotrophoblast cells (pg. 5, lines 19, 20). Thus, detecting the presence or

absence of invasive trophoblast cells is inherent in the method of Cole et al. Thus, Cole et al. anticipates the claimed method of detecting the presence or absence of invasive trophoblast cells in a biological, urine sample comprising the aforementioned steps.

Summary

No claims are allowed.

Claims 9 and 16 are free of the prior art. The closest prior art is Kobata (Biochimie, 1988, 70: 1575-1585) which does not teach or suggest the limitation wherein the gestational trophoblastic disease is a placenta-site tumor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

PJR